

**B. PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### Haemaccel (Polygeline)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

- 1. What Haemaccel is and what it is used for**
- 2. What you need to know before you take Haemaccel**
- 3. How to take Haemaccel**
- 4. Possible side effects**
- 5. How to store Haemaccel**
- 6. Contents of the pack and other information**

#### 1. What Haemaccel is and what it is used for

Haemaccel contains the active substance Polygeline.

Haemaccel is one of a group of medicines called “plasma substitutes”. It is used to provide fluid to a patient in a number of situations, for example: a) to replace fluid which has been lost due to bleeding (e.g. haemorrhage, child birth or during gynaecological procedures), burns or inflammation. b) To provide fluid to an organ during an operation on that organ c) to provide fluid for an insulin injection. Ask your doctor or nurse for more information if you have any questions.

#### 2. What you need to know before you take Haemaccel

Do not use Haemaccel

- If you are allergic to Haemaccel or any of its ingredients of this medicine (listed in section 6)
- If you have any allergies and/or are you currently experiencing any allergic reactions(s)
- If you have difficulty breathing
- If you have any kidney disease
- If you are intolerant to in injections
- If you have a tendency to bleed or do you have any inherited bleeding disorder (e.g. haemorrhagic diathesis)
- If you have any heart condition
- If you have hypertension (high blood pressure)
- If you have any varices (enlarged veins)
- If you suffer from oedema (swelling due to fluid retention)

If you think any of the above statements applies to you, then discuss the situation with your doctor or nurse.

#### Warnings and precautions

Talk to your doctor or nurse before taking Haemaccel.

In the following cases, Haemaccel is indicated to a restricted extent, if the physician considers the infusion necessary, it should be given taking special precautions.

- All conditions in which an increase in intravascular volume and its consequences (e.g. increased stroke volume, elevated blood pressure), or an increase in interstitial fluid volume, or haemodilution could represent a special risk for the patient. Examples of such conditions are: congestive heart failure, hypertension, oesophageal varices, pulmonary oedema, haemorrhagic diathesis, renal and post-renal anuria.
- In all patients at an increased risk of histamine release (e.g. allergic persons and patients with a history of histamine response; also patients who in the previous 7 days have received a drug which releases histamine). In the latter cases, Haemaccel may be given only after taking appropriate prophylactic steps. Reactions caused by histamine release can be avoided by the prophylactic use of H1 and H2 receptor antagonists. Inappropriate rapid administration of Haemaccel, especially to normovolaemic patients may cause the release of vasoactive substances. The exact mechanism of this histamine release has not been clearly defined.

### **Other medicines and Haemaccel**

**Tell your doctor if you are taking, have recently taken or might take any other medicines.**

**In particular, tell your doctor if you are taking :** cardiac glyco-sides to treat a heart condition (e.g. digoxin or digitoxon); anaesthetics; muscle relaxants; pain killers; drugs to treat hypotension (e.g. trimetaphan camsylate); or anticholinergics.

### **Pregnancy and breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Haemorrhage around the time of childbirth or blood loss during other obstetric or gynaecological procedures may necessitate plasma volume replacement. Haemaccel has been used for many years for the initial treatment in such cases without apparent ill consequence.

If plasma volume replacement is needed during pregnancy, Haemaccel may be used if blood is not available.

**Haemaccel contains sodium chloride and potassium chloride:** Haemaccel contains 4.25g sodium chloride & 0.20g potassium chloride per 500 ml

This medicinal product contains approximately 0.1847 mmol sodium in each 500 ml vial. This should be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains approximately 0.005 mmol potassium in each 500 ml vial. This should be taken into consideration by patients on a controlled potassium diet.

### **3. How to take Haemaccel**

Haemaccel will usually be given to you by intravenous infusion (drip). The dose given will depend on your condition.

A typical infusion rate will be 500 ml of Haemaccel over 1 hour. However, Haemaccel may be given to you more rapidly in an emergency situation.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects to Haemaccel may include:

- Hypotension (e.g. dizziness on standing)
- Skin rash (e.g. wheals)
- Hypercalcaemia (increased level of calcium in blood)
- Increased temperature and/or shivering
- Shortness of breath or breathing difficulties.
- Nausea and vomiting

- A change in heart beat (e.g. heart murmur or flutter)

In rare cases, you may experience a hypersensitivity reaction to Haemaccel, resulting in shock. If this happens, your doctor or nurse will give you appropriate treatment to remedy this. If you experience any of the above side effects or any other unusual or unexpected symptoms, then tell your doctor or nurse.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Haemaccel**

You will not normally be asked to store your medicine as it will be given to you by the doctor. There are no special storage instructions for Haemaccel. Haemaccel contains no preservatives; therefore any unused fluid should be discarded once the bottle has been opened.

Do not use this medicine after the expiry date which is stated on the label 'EXP'. The expiry date refers to the last day of that month.

Remember this medicine is for you. Only a doctor can prescribe it to you. Keep this medicine out of the sight and reach of children. This leaflet does not contain all the information about your medicine. If you have any question or are not sure about anything, ask your doctor or nurse, who have access to additional information. This leaflet only applies to Haemaccel.

### **6. Contents of the pack and other information**

#### **What Haemaccel contains**

- The active substance is polygeline.
- The other ingredient(s) are sodium chloride, potassium chloride, calcium chloride and water for injection

#### **What Haemaccel looks like and contents of the pack**

Haemaccel comes as a 500 ml solution in plastic bottles.

#### **Marketing Authorization Holder**

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